



POST-ASH ONCOLOGY-HEMATOLOGY REVIEW

DECEMBER 8, 2020

AMGEN[®]

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No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

AGENDA

Introduction

**David Reese, M.D.—Executive Vice President,
Research and Development**

Oncology- Hematology Update

**Gregory Friberg, M.D.—Vice President, Global
Development and Oncology Therapeutic Area Head**

Q&A

**David Reese, M.D.
Gregory Friberg, M.D.**



INTRODUCTION

DAVID REESE, M.D.

EXECUTIVE VICE PRESIDENT, RESEARCH AND DEVELOPMENT



AMGEN ONCOLOGY-HEMATOLOGY: A BROAD, DIFFERENTIATED PORTFOLIO

- Built on first-in-class molecules directed against high-quality targets in areas of high unmet need
- Developing combination/sequential therapies against multiple targets and indications to drive deep, durable responses
- Prioritizing high-potential programs for rapid advancement
 - First-in-class KRAS^{G12C} inhibitor sotorasib
 - BiTE[®] immuno-oncology platform clinically validated in solid and hematologic tumors

KRAS = Kirsten rat sarcoma viral oncogene homolog; BiTE[®] = bispecific T-cell engager

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SOTORASIB (AMG 510): A FIRST-IN-CLASS KRAS^{G12C} INHIBITOR ADVANCING RAPIDLY THROUGH CLINICAL DEVELOPMENT

- **Highly selective, irreversible inhibitor of KRAS^{G12C}**
- **Only once-daily oral dosing option**
- **Broadest KRAS^{G12C} program with > 600 patients across four continents**
- **First KRAS^{G12C} inhibitor in the clinic with the largest dataset**
 - **Durable objective responses in 2nd-line+ NSCLC**
 - **Objective responses across a broad range of mutational profiles and subgroups with poor prognosis (i.e., brain metastases)**
- **Well-tolerated safety profile**
 - **Low rate of dose reductions and discontinuations**
 - **No treatment-related deaths**
 - **No QTc prolongation, low and manageable GI toxicities**

NSCLC = non-small cell lung cancer; QTc = corrected QT interval; GI = gastrointestinal

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SOTORASIB:

THE BROADEST, MOST ADVANCED, GLOBAL KRAS^{G12C} CLINICAL PROGRAM

Clinical Trial	ClinicalTrials.gov NCT ID	Treatments	Advanced KRAS G12C-Mutated Cancers			Phase
			NSCLC	CRC	Other Solid Tumors	
CodeBreak 200	NCT04303780	Monotherapy vs. docetaxel				3
		Monotherapy				2
CodeBreak 100	NCT03600883	Monotherapy				1
		+ PD-1/PD-L1 inhibitor				1
CodeBreak 101	NCT04185883	+ Pan-ErbB TKI				1b
		+ PD-L1 inhibitor				1b
		+ Chemotherapy				1b
		+ EGFR Ab +/- Chemotherapy				1b
		+ PD-1 inhibitor				1b
		+ MEK inhibitor				1b
		+ SHP2 inhibitor				1b
		+ mTOR inhibitor				1b
CodeBreak 105	NCT04380753	+ CDK inhibitor				1b
		Monotherapy*				1

NCT = National Clinical Trial number; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; PD-1 = programmed death-1; PD-L1 = programmed death ligand-1; ErbB = erythroblastic leukemia viral oncogene homolog; TKI = tyrosine kinase inhibitor; EGFR Ab = epidermal growth factor receptor antibody; MEK = mitogen-activated protein kinase kinase; SHP2 = Src homology region 2-containing protein tyrosine phosphatase 2; mTOR = mammalian target of rapamycin; CDK = cyclin-dependent kinase; *In subjects of Chinese descent

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SOTORASIB UNDER REAL-TIME REVIEW BY FDA FOR TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER

- **Breakthrough Therapy Designation granted by FDA**
 - For the treatment of patients with locally advanced or metastatic non-small cell lung cancer with *KRAS G12C* mutation, as determined by an FDA-approved test, following at least one prior systemic therapy
 - Designed to expedite development and regulatory review of drugs for serious or life-threatening conditions
 - Eligible for all Fast Track designation features
- **Accepted into Real-Time Oncology Review pilot program**
 - Initiated transfer of data packages to FDA

Submission of complete New Drug Application planned by year end



ONCOLOGY-HEMATOLOGY UPDATE

GREGORY FRIBERG, M.D.

VICE PRESIDENT, GLOBAL DEVELOPMENT AND ONCOLOGY
THERAPEUTIC AREA HEAD

AMGEN[®]

ADVANCING FIRST-IN-CLASS MOLECULES AGAINST HIGH-QUALITY TARGETS FOR BOTH SOLID AND HEMATOLOGIC MALIGNANCIES

Solid Tumors				Hematologic Malignancies			
Tumor Type	Molecule	Target	Modality	Tumor Type	Molecule	Target	Modality
Solid Tumors	Sotorasib	KRAS G12C	Small Molecule	Multiple Myeloma	AMG 701	BCMA	HLE-BiTE® Molecule
Prostate Cancer	AMG 160	PSMA	HLE-BiTE® Molecule		AMG 330	CD33	BiTE® Molecule
	AMG 509	STEAP1	XmAb® 2+1 Bispecific Ab	AMG 673	CD33	HLE-BiTE® Molecule	
Small Cell Lung Cancer	AMG 757	DLL3	HLE-BiTE® Molecule	Acute Myeloid Leukemia	AMG 427	FLT3	HLE-BiTE® Molecule
Gastric or Gastroesophageal Junction Cancer	AMG 199	MUC17	HLE-BiTE® Molecule	AMG 176	MCL1	Small Molecule	
	AMG 910	CLDN18.2	HLE-BiTE® Molecule	AMG 397	MCL1	Small Molecule	
Glioblastoma	AMG 596	EGFRvIII	BiTE® Molecule	Acute Lymphoblastic Leukemia	BLINCYTO®	CD19	BiTE® Molecule
Melanoma	IMLYGIC®		Oncolytic Virus				

BCMA = B-cell maturation antigen; HLE = half-life extended; BiTE® = bispecific T-cell engager; CD = cluster of differentiation; CLDN = claudin; DLL3 = delta-like ligand 3; EGFRvIII = epidermal growth factor receptor variant III; FLT3 = FMS-like tyrosine kinase 3; MUC = mucin; PSMA = prostate-specific membrane antigen; STEAP1 = six transmembrane epithelial antigen of the prostate 1

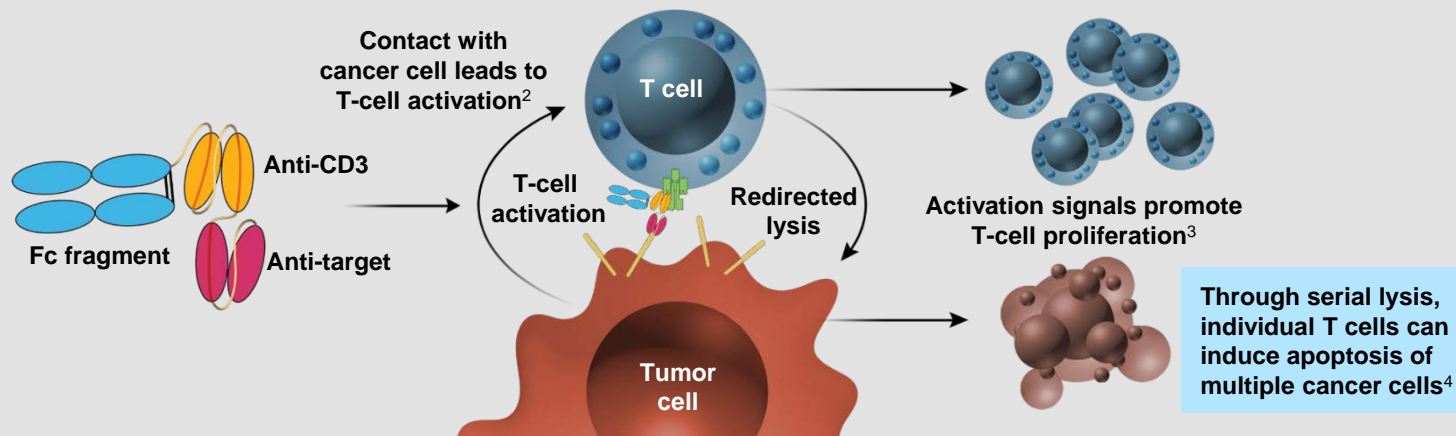
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AMGEN'S BiTE[®] PLATFORM: A CLINICALLY VALIDATED IMMUNO-ONCOLOGY THERAPY

- **Clinically validated, off-the-shelf immuno-oncology therapy**
 - > 3,000 patients treated with BiTE[®] therapies to date
- **Seamlessly integrated, scalable, industrialized platform**
- **Clinical activity demonstrated in both liquid and solid tumors**
 - Advancing programs against high-quality targets in prostate cancer, small cell lung cancer, multiple myeloma and gastric cancer
- **Applying learnings across programs to optimize dose/schedule and mitigate adverse events**
- **Exploring combination/sequential therapy strategies to prevent resistance**

AMGEN BITE[®] (BISPECIFIC T-CELL ENGAGER) IMMUNOTHERAPY



- BiTE[®] molecules engage a patient's own T cells to attack and eradicate cancer cells¹
 - T-cell activation induces transient cytokine release and tumor killing¹
- BLINCYTO[®] (blinatumomab) is the first and only bispecific immunotherapy approved in oncology worldwide¹

1. Baeuerle PA, et al. *Cancer Res.* 2009;69:4941-4944. 2. Klinger M, et al. *Immunol Rev.* 2016;270(1):193-208. 3. Bargou R, et al. *Science.* 2008;321:974-977. 4. Stiegelmaier J, et al. *Expert Opin Biol Ther.* 2015;15(8):1093-1099.



**AMG 160 AND AMG 509
FOR PROSTATE CANCER**

AMGEN[®]

PROSTATE CANCER IS A LEADING CAUSE OF MORTALITY IN MEN, REPRESENTING A HIGH UNMET MEDICAL NEED

- Prostate cancer is a highly prevalent disease
 - #1 non-cutaneous cancer in men in the U.S. and EU, #2 worldwide¹⁻⁴
 - ~ 1.3 million diagnoses and ~ 360,000 deaths worldwide in 2018⁵
 - Despite androgen-deprivation therapy, most men progress to castrate-resistant prostate cancer (CRPC)⁶, and ~ 1/3 develop metastases within two years⁷
- Metastatic CRPC (mCRPC) remains incurable despite current treatments⁸
 - The five-year survival rate for mCRPC is 30%²

ADVANCING PSMA-TARGETING HLE-BITE[®] MOLECULE AMG 160 INTO DOSE EXPANSION FOR MCRPC

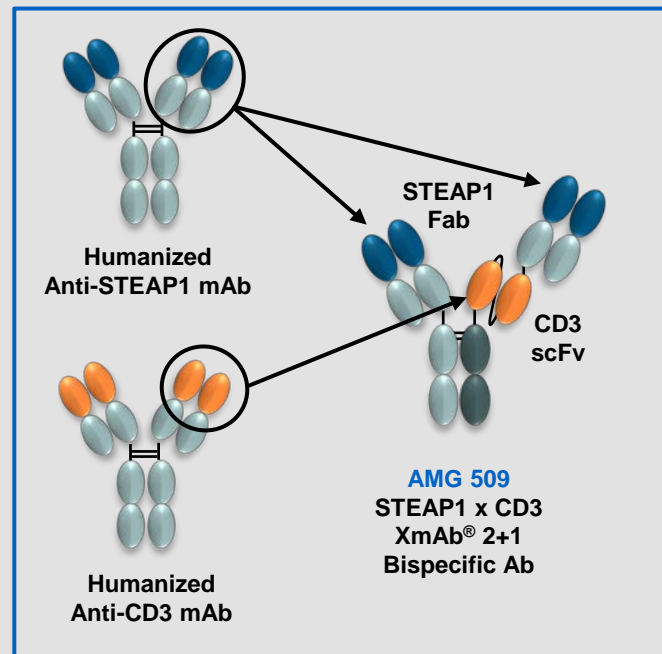
- **AMG 160 showed preliminary evidence of efficacy in 43 heavily pretreated patients¹**
 - PSA declines in 68.6% of patients across all monotherapy dose cohorts
 - 34.3% of patients with \geq PSA50 reduction
 - Three PR (two confirmed) and eight SD in 15 patients with measurable disease
- **Manageable monotherapy safety profile**
 - CRS was reversible and manageable with priming doses and standard mitigations
 - No grade 5 TRAEs or treatment-related discontinuations
 - Improved CRS profile and reduced anti-drug Ab formation with recent dose optimization

Initiating dose expansion cohort

PSA = prostate-specific antigen; PSA50 = PSA decrease of \geq 50%; PR = partial response; SD = stable disease; CRS = cytokine release syndrome; TRAE = treatment-related adverse event; Ab = antibody; 1. Tran et al. ESMO 2020
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AMG 509: A NOVEL STEAP1-TARGETING IMMUNOTHERAPY IN PHASE 1 DEVELOPMENT FOR CRPC

- **STEAP1 is an integral membrane protein expressed at low levels in normal tissue and highly upregulated in mCRPC tumors**
 - Metastatic lesions express higher levels of STEAP1 than primary tumors
- **AMG 509 is a bispecific XmAb[®] 2+1 immune therapy designed to redirect cytotoxic T cells to STEAP1+ tumor cells**
 - In preclinical studies, AMG 509 triggered potent T cell-redirected lysis of STEAP1+ cancer cells¹
 - Phase 1 study currently enrolling patients



STEAP1 = six transmembrane epithelial antigen of the prostate 1; ¹Nolan-Stevaux, AACR Virtual Meeting II, June 22 - 24, 2020

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**AMG 757 FOR SMALL CELL
LUNG CANCER**

AMGEN[®]

SMALL CELL LUNG CANCER (SCLC) IS AN AGGRESSIVE TUMOR WITH POOR PROGNOSIS AND FEW TREATMENT OPTIONS¹

- **SCLC accounts for ~ 13% of the ~ 230,000 lung cancer cases diagnosed annually in the U.S.²**
 - **Chemotherapy has remained the standard treatment for over four decades³**
 - **Immune therapies assessed to date have limited benefit³ with overall survival of ~ one year or less⁴**
- **Delta-like ligand 3 (DLL3) is an inhibitory Notch ligand expressed at low levels in normal tissue and highly upregulated in SCLC tumors⁵**
- **AMG 757 is a half-life extended BiTE[®] immune therapy designed to redirect cytotoxic T cells to DLL3+ tumor cells**

1. van Meerbeeck JP, et al. *Lancet*. 2011;378:1741-1755. 2. <https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html>. 3. Taniguchi H, et al. *Front Oncol*. 2020;10:741.

4. Rossi A. *Eur Med J*. 2019;4(2):45-53.; 5. Leonetti A, et al. *Cell Oncol (Dordr)*. 2019;42:261-273.

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AMG 757 DEMONSTRATED ANTITUMOR ACTIVITY WITH AN ACCEPTABLE SAFETY PROFILE IN SCLC PATIENTS

- **Confirmed ORR 16% (6 partial responses/38 evaluable patients) across all doses in Phase 1¹**
 - Apparent dose response with 5/18 responses (27.8%) at higher doses (1–10 mg)
 - 5/6 partial responders still receiving therapy with ongoing response
 - Median follow-up time was 8.8 months; duration of response 1.9+ to 9.4+ months
 - 4-week disease control rate 45%
- **Reversible and manageable grade 1 or 2 CRS in 45% of patients**
- **The maximum tolerated dose for AMG 757 has not been reached; dose optimization is ongoing**

ORR = overall response rate; 1. Borghaei et al. SITC 2020

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AMG 701 FOR MULTIPLE MYELOMA

AMGEN[®]

A PHASE 1 FIH STUDY OF AMG 701, AN ANTI-BCMA HALF-LIFE EXTENDED (HLE) BITE[®] (BISPECIFIC T-CELL ENGAGER) MOLECULE, IN RELAPSED / REFRACTORY MULTIPLE MYELOMA

Simon J. Harrison,¹ Monique C. Minnema,² Hans C. Lee,³ Andrew Spencer,⁴ Prashant Kapoor,⁵ Deepu Madduri,⁶ Jeremy Larsen,⁷ Sikander Ailawadhi,⁸ Jonathan Kaufman,⁹ Marc S. Raab,¹⁰ Parameswaran Hari,¹¹ Shinsuke Iida,¹² Ravi Vij,¹³ Faith E. Davies,¹⁴ Robin Lesley,¹⁵ Vijay V. Upreti,¹⁶ Zhao Yang,¹⁷ Anjali Sharma,¹⁸ Alex C. Minella,¹⁸ Suzanne Lentzsch¹⁹

¹Clinical Haematology, Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne, Australia, Sir Peter MacCallum Dept of Oncology, Melbourne University, Melbourne, Australia, ²University Medical Center Utrecht, University Utrecht, Utrecht, Netherlands, ³The University of Texas M. D. Anderson Cancer Center, Houston, TX, USA, ⁴Alfred Hospital-Monash University, Melbourne, Australia, ⁵Mayo Clinic, Rochester, MN, USA, ⁶Icahn School of Medicine at Mount Sinai, New York, NY, USA, ⁷Mayo Clinic, Phoenix, AZ, USA, ⁸Mayo Clinic, Jacksonville, FL, USA, ⁹Emory University, Atlanta, GA, USA, ¹⁰Heidelberg University Hospital, Heidelberg, Germany, ¹¹Medical College of Wisconsin, Milwaukee, WI, USA, ¹²Nagoya City University Hospital, Nagoya, Japan, ¹³Washington University School of Medicine, St. Louis, MO, USA, ¹⁴NYU Langone, New York, NY, USA, ¹⁵Clinical Biomarkers and Diagnostics, Amgen Inc., South San Francisco, CA, USA, ¹⁶Clinical Pharmacology, Modeling & Simulation, Amgen Inc., South San Francisco, CA, USA, ¹⁷Global Biostatistical Science, Amgen Inc., Thousand Oaks, CA, USA, ¹⁸Early Development, Oncology, Amgen Inc., Thousand Oaks, CA, USA, ¹⁹Columbia University Medical Center, New York, NY, USA

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AMG 701 FIRST-IN-HUMAN DATA SUMMARY

- **In 85 patients with heavily pretreated (median six prior therapies) relapsed/refractory multiple myeloma, AMG 701 demonstrated**
 - **A manageable safety profile**
 - All grade 3 CRS events were reversible with a median duration of two days; 50% of grade 3 CRS designations were driven by transient LFT increases
 - **Encouraging activity with responses lasting up to 26 months**
 - 83% ORR (5/6) at the most recent evaluable cohort
 - 6/7 patients tested for minimal residual disease (MRD) were MRD-
 - Predictable PK profile supportive of once-weekly dosing
- **Dose optimization of AMG 701 is ongoing**

LFT = liver function test; PK = pharmacokinetics

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**BLINCYTO[®] FOR ACUTE
LYMPHOBLASTIC LEUKEMIA**

AMGEN[®]

SUPERIOR EVENT-FREE SURVIVAL WITH BLINATUMOMAB VERSUS CHEMOTHERAPY IN CHILDREN WITH HIGH-RISK FIRST RELAPSE OF B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA: A RANDOMIZED, CONTROLLED PHASE 3 TRIAL

Franco Locatelli[†], Gerhard Zugmaier, Carmelo Rizzari, Joan Morris, Bernd Gruhn, Thomas Klingebiel, Rosanna Parasole, Christin Linderkamp, Christian Flotho, Arnaud Petit, Concetta Micalizzi, Noemi Mergen, Abeera Mohammad, William Kormany, Cornelia Eckert, Anja Möricke, Mary Sartor, Ondrej Hrusak, Christina Peters, Vaskar Saha, Luciana Vinti, and Arend von Stackelberg

¹Department of Pediatric Hematology/Oncology, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy, ²Amgen Research (Munich) GmbH, Munchen, Germany, ³San Gerardo Hospital, University of Milano-Bicocca, Monza, ITA, ⁴Amgen Inc., Thousand Oaks, CA, ⁵Department of Pediatrics, Department of Pediatrics, Jena, Germany, ⁶Department for Children and Adolescents, University Hospital Frankfurt, Frankfurt am Main, Germany, ⁷Dept Pediatric Hemato-Oncology, Azienda Ospedaliera di Rilievo Nazionale Santobono Pausilipon, Napoli, Italy, NAPOLI, Italy, ⁸Medizinische Hochschule Hannover, Hanover, Germany, ⁹Division of Pediatric Hematology and Oncology, Department of Pediatrics and Adolescent Medicine, Medical Center, Faculty of Medicine, University of Freiburg, Freiburg, Germany, ¹⁰Hopital Trousseau, PARIS, France, ¹¹Istituto Pediatrico di Ricerca e Cura a Carattere Scientifico G Gaslini, Genova, Italy, ¹²Amgen Research (Munich), Munich, Germany, ¹³Global Biostatistical Science, Amgen Ltd, Uxbridge, United Kingdom

¹⁴Department of Pediatric Oncology/Hematology, Campus Rudolf Virchow, Charité University Hospital, Berlin, Germany, ¹⁵Department of Pediatrics, University Medical Center of Schleswig-Holstein, Campus Kiel, Kiel, Germany, ¹⁶Westmead Institute for Medical Research, Sydney, Australia, ¹⁷CLIP - Childhood Leukaemia Investigation Prague, Department of Paediatric Haematology and Oncology, Charles University CLIP, Prague, Czech Republic, ¹⁸St Anna's Childrens Hospital, Vienna, Austria, ¹⁹Tata Translational Cancer Research Centre, Tata Medical Center, Kolkata, India, ²⁰Department of Pediatric Oncology/Hematology, Charite Medical Center, Berlin, Germany

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BLINATUMOMAB WAS SUPERIOR TO CHEMOTHERAPY AS CONSOLIDATION BEFORE STEM CELL TRANSPLANT

- Blinatumomab demonstrated superior event-free survival (HR 0.33, 95% CI 0.18–0.61, $p < 0.001$) and superior MRD remission (90% vs. 54%)
 - Positive overall survival trend in blinatumomab arm (HR 0.43, 95% CI 0.18–1.01)
- Grade ≥ 3 treatment-related adverse events were higher in the chemotherapy arm than blinatumomab arm (82% vs. 57%, respectively)
- As expected, grade ≥ 3 neurologic events occurred more frequently with blinatumomab (6%) than with chemotherapy (2%)
- No grade 3 or higher cytokine release syndrome (CRS) events were reported

Blinatumomab constitutes a potential new standard of care in children with high-risk, first-relapse ALL

HR = hazard ratio; CI = confidence interval; ALL = acute lymphoblastic leukemia

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Q&A

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